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S. Robert Chuey	39,140
Name of Attorney	Registration No.
Signature of Attorney	

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of :
GARY (NMN) STEPHENSON : Confirmation No. 5677
Serial No. 09/489,310 : Group Art Unit 1614
Filed January 21, 2000 : Examiner: S. Rose
For METHODS OF USING A BEVERAGE COMPOSITION

APPELLANT'S BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant hereby appeals to the Board of Appeals the decision of the Examiner dated January 9, 2003, finally rejecting Claims 11 -15, 17 - 20, and 22 - 31. The Notice of Appeal was timely filed and received in the US Patent and Trademark Office on April 14, 2003 (a copy of the return postcard is enclosed). The two-month anniversary of the receipt of the Notice of Appeal fell on Saturday, June 14, 2003, and this Brief is filed on Monday, June 16, 2003. As such, the present Appeal Brief is believed to be timely filed. This Brief is being filed in triplicate.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company, assignee of Appellant's entire right, title, and interest in the invention at issue. The Assignment to the Procter & Gamble Company for this case is recorded at the Patent and Trademark Office at Reel 013571 and Frame 0346.

RELATED APPEALS AND INTERFERENCES

Appellant, Appellant's undersigned legal representative and the Assignee are not aware of any pending appeals or interferences that would be directly affected by or have a bearing on the Board's decision in the subject Appeal.

STATUS OF CLAIMS

Claims 11 -15, 17 - 20, and 22 - 31 are the subject of this appeal. No other claims are pending or allowed. Claims 1-10, 16 and 21 were cancelled during prosecution. Claims 11 - 15,

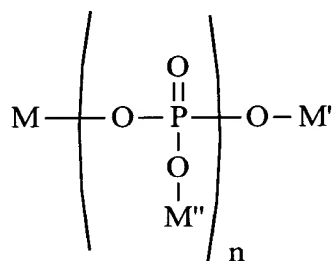
17 - 20 and 22 - 31 were finally rejected in the Final Office Action dated January 9, 2003. The claims on appeal are set forth in the Appendix.

STATUS OF AMENDMENTS

No amendments were filed or proposed after the Final Office Action in this case. And it is believed that all previous amendments have been entered and considered.

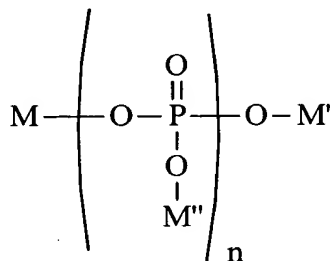
SUMMARY OF THE INVENTION

The present invention is related to a kit comprising a beverage composition and information that use of the beverage composition provides treatment against dental erosion. The beverage composition has a pH of less than about 5 and it comprises a compound having the structure:



In the formula above, n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium. Further, the beverage composition is substantially free of calcium and fluoride and comprises less than about 0.025% of orthophosphate, by weight of the composition.

In another aspect of the present invention there is a method of treating dental erosion comprising orally administering to a mammal a beverage composition that has a pH of less than about 5 and is substantially free of calcium and fluoride. Further the beverage composition comprises a compound having the structure:



In this structure n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium.

ISSUES

As a matter of law, are “kit” claims patentable?

Are Claims 11 –15, 17 – 20, and 22 – 31 novel over 11 different US Patents, under 35 U.S.C. § 102 (a), (b), or (e)?

Are Claims 11 –15, 17 – 20, and 22 - 31 obvious over US Patents to Calderas and Smith et al., in combination with Shibata et al., McGaughey, or Harris, further in light of Muhler and McDonald, under 35 U.S.C. § 103 (a)?

GROUPING OF CLAIMS

Claims 11-15, and 17-20 and 22, which are directed to kits comprising a composition and information about the composition, stand or fall together. Claims 23-31, which are directed to methods of using a composition, stand or fall together.

ARGUMENTS

A. The Examiner’s Rejection

The Examiner has rejected Claims 11 –15, 17 – 20, and 22 – 31 as allegedly lacking novelty over 11 different US Patents, under 35 U.S.C. § 102 (a), (b), or (e). And the Examiner has further rejected Claims 11 –15, 17 – 20, and 22 - 31 as allegedly obvious under 35 U.S.C. § 103 (a) over the combination of 1) US Patents to Calderas and Smith et al., 2) in combination with Shibata et al., McGaughey, or Harris, and 3) further in light of Muhler and McDonald. Much of the Final Office Action, however, deals with the Examiner’s stated premise that “printed matter” should be given no patentable weight. As such, the Examiner asserts, “Kit” claims containing such printed matter, are *per se*, unpatentable.

B. The Prior Art

The Beverage Art

Calderas, Smith et al., Montezinos (I and II), Ekanayake et al., McKenna et al., Tung et al., Cirigliano et al. (I and II), Sokolik et al., and Zablocki et al.

All 11 of these US Patents are relied on for their teaching of low pH, sweetened, fruit juice containing beverages. The patent numbers are listed on the PTO-892 form, but Appellant does not dispute that the polyphosphates of the present claims are taught in these references for use in beverages. Because the content of these 11 references is not in dispute, they will not be discussed in great detail in Appellant’s Brief. Appellant does dispute, however, as is discussed in greater detail below, the Examiner’s legal premise for extrapolating the teachings of these references to reject the present claims. Specifically, there is no any teaching or suggestion of the

prevention of tooth erosion in any of these references. As such, the “information” of the present kit claims and the method steps of the present method claims are not taught or suggested by these references.

The Caries Art

Shibata et al., McGaughey, and Harris.

Shibata, H., and Morioka T., “Antibacterial Action of Condensed Phosphates on the Bacterium *Streptococcus Mutans* and Experimental Caries in the Hamster” *Archives of Oral Biology*, Vol. 27, pp. 809-816 Published in Brazil, 1982 (referred to as “Shibata”). McGaughey *et al.*, “Effects of Polyphosphates on the Solubility and Mineralization of HA: Relevance to a Rationale for Anticaries Activity,” *Journal of Dentistry Research*, Vol. 56, No. 6, pp. 579 – 587 (June 1977) (herein referred to as “McGaughey”). Harris, R. S. *et al.*, “The Effect of Phosphate Structure on Dental Caries Development in Rats”, *Journal of Dentistry Research*, Vol. 46, pp. 290-294, published 1967 (referred to as “Harris”).

These three journal articles are relied upon by the Examiner for the teaching of the use of mono, tri and hexa phosphates for caries prevention. The phosphate compounds are used relatively neutral pH (above 5.0 pH) dentrifice compositions, for example, toothpaste. These articles do not teach the polyphosphates of the present claims, that is, poly phosphates with n greater than or equal to 7. Nor do these references teach the use of any phosphate containing compounds in beverages. Dental erosion is not discussed in these references.

Dental Erosion Art

Muhler and McDonald.

Muhler, ZA 6904743, published 1972 (referred to as “Muhler”) and McDonald *et al.*, “Laboratory Studies Concerning the Effect of Acid-Containing Beverages on Enamel Dissolution and Experimental Dental Caries”, *J. Dent. Res.*, pp. 211 – 216, published 1973 (referred to as “McDonald”).

These two Journal articles are relied upon for the teaching of phosphate ions, delivered from a mono phosphate compound, for the prevention of tooth erosion. These articles do not teach the polyphosphates of the present claims, that is, poly phosphates with n greater than or equal to 7. Nor do these references teach the use of any phosphate containing compounds in beverages.

C. Argument: The Rejection Under 35 U.S.C. § 102(a)

The Examiner has rejected Claims 11 –15, 17 – 20, and 22 – 31 as allegedly lacking novel over 11 different US Patents, under 35 U.S.C. § 102 (a), (b), or (e). The 11 patents all

belong to the beverage art and they teach nothing about dental erosion or prevention thereof. As discussed above, in the brief summary of the Prior Art, the beverage art does not disclose a method for treating dental erosion or a kit containing information that use of the beverage composition provides treatment against dental erosion. As such, the present rejection under § 102 is improper and must be overturned.

The Examiner, while admitting that the references are silent regarding any teaching or suggestion of the prevention of dental erosion, states that the portion of the present claims dealing with the prevention of dental erosion is simply "printed matter" and is entitled to no patentable weight. The Examiner cites *In re Haller*, 73 USPQ 403 (CCPA 1947). The Examiner has cited *Haller* for the premise that novelty cannot be predicated on printed instructions.

Appellant traverses this rejection and the Examiner's reliance on *Haller*. Appellant cites the more contemporary cases *In re Miller*, 164 USPQ 46 (CCPA 1969) and *In re Gulack*, 217 USPQ 401 (Fed. Cir. 1983), which were both decided subsequent to *Haller*. In response to these more recent cases the Examiner states that the reliance on *Haller* is justified because it has not been overturned. While this is technically true, *Haller* was decided 5 years before the 1952 Patent Act. The Board's attention is directed to Footnote 8 of *In re Gulack*, where the Court of Appeals for the Federal Circuit states (emphasis added):

"A "printed matter rejection" under § 103 stands on questionable legal and logical footing. Standing alone, the description of an element of the invention as printed matter tells nothing about the differences between the invention and the prior art or about whether that invention was suggested by the prior art. A printed matter rejection is based on case law antedating the 1952 patent act, employing a point a novelty approach....The 1952 act legislatively revised this approach through its requirement that the claim be viewed as a whole in determining obviousness."

While, of course, this footnote refers to a § 103 rejection, the legal theory remains the same. The 1952 Patent Act codified a position on printed matter that is contrary to *Haller*, which effectively overturned this decision. The more recent case law on this point, *In re Gulack* and *In re Miller* both support Appellant's position that the printed matter portion of the present claims are not only entitled to patentable weight, but also distinguish the present claims over the art cited by the Examiner.

More specifically, in *Gulack* and *Miller* an apparatus comprising previously known items, in association with information which was functionally related to those items, were held novel and non-obvious over the known items. For example, in *Miller*, which related to printed information on a measuring device, the Court stated:

[The Examiner's] characterization of printed matter as "unpatentable" is beside the point; no attempt is here being made to patent printed matter as such. The fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination. Here there is a new and unobvious functional relationship between a measuring receptacle, volumetric indicia thereon . . . and a legend indicating the ratio, and in our judgment the appealed claims properly define this relationship.

See Miller, at third paragraph from conclusion of opinion (emphasis added).

Indeed, the PTO supports *Miller*, and *only* directs claim rejections in view of 35 U.S.C. 101 and *Miller* when a mere arrangement of printed matter is claimed. See MPEP 706.03(a).

The Federal Circuit affirmed *Miller* in *Gulack*, even while recognizing that the "sole difference" between the claimed article and the prior art composition was the printed material. In *Gulack*, the Federal Circuit stated:

A functional relationship of the precise type found by the CCPA in *Miller* – to size or to type of substrate, or conveying information about [the] substrate – is not required. What is required is the existence of differences between the appealed claims and the prior art sufficient to establish patentability.

See *Gulack*, Section II, B.

Taken in the context of the present invention, Claims 11 – 15, 17 – 20, and 22 – 31 are indeed patentable over the cited U.S. patents. The information referred to in independent Claims 11 and 23, *i.e.*, information and method steps that use of the beverage composition provides treatment against dental erosion, is clearly functionally related to the beverage composition itself. It is representative of the present discovery that the polyphosphate compounds recited in the claims are surprisingly effective against dental erosion. Moreover, the kits and methods of Claims 11 – 15, 17 – 20, and 22 – 31 are directive, such that a consumer will understand the present discovery and have the ability to capitalize on such discovery. Thus, the utility of the present compositions is furthered because the consumer will understand the benefits, and be encouraged to utilize, the beverage composition based on this surprising and previously unknown use.

Finally, the Examiner, again admitting that the references relied upon to reject the present claims fail to teach any of the limitations that deal with dental erosion, suggests that these characteristics are inherently present in the prior art. Appellant asserts that any rejection of the present Claims based on inherency and in view of any of the U.S. Patents cited on Examiner's Form PTO-892, is untenable and should be overturned. The present kit and method claims are not anticipated based on inherency because each and every element of the claims is not disclosed in any of the cited patents, either expressly or inherently. See *Verdegaal Bros. v. Union Oil Co.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Indeed, a key limitation of kit Claims 11 – 15, 17 – 20, and 22, and the method claims of 23-31 is “*information* that use of the [recited] beverage composition provides treatment against dental erosion.” and “A method of treating dental erosion comprising orally administering to a mammal a beverage composition”. These limitations (the *information* and method in association with the recited composition) are not taught, suggested, or even inherently present in any of the cited patents. But the Examiner asserts that this information is inherent in the teachings of the prior art. The Examiner appears to take two mutually inconsistent positions. First, the “information” and “methods” of the present invention are ignored as simply “printed matter” not entitled to any patentable weight, then the Examiner suggests that this “printed matter” is inherent in the prior art. Printed matter, being a visible and tangible item by definition, is either present in the prior art or it is not. And by resorting to an inherency rejection, the Examiner admits that it is not present. Moreover, there is no extrinsic evidence which may be used to show that the missing descriptive matter is necessarily, or even possibly, present in the cited patents. *See Continental Can Co. v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Accordingly, the cited case law of *Atlas Powder* and *Ex parte Novitski* is irrelevant in view of the presently pending claims, as there is *no inherent presence of the claimed subject matter* set forth in the patent references presented by the Examiner. Any rejection of Claims 11 – 15, 17 – 20, and 22-31 based on inherency is therefore misplaced and should be overturned.

Appellant asserts that there are indeed differences between the cited art and the presently claimed kits and methods, rendering these kits and methods novel and unanticipated under 35 U.S.C. § 102. Like *Gulack* and *Miller*, the differences are largely related to the *information*. Moreover, this information is functionally related to the beverage of the recited kits (as highlighted in *Gulack*, yet “not required” under *Miller*). This information is a reflection of the present discovery that the recited compositions are surprisingly useful against dental erosion; Appellant has a legal right to protect this novel discovery. Appellant finds nothing in *Gulack* and *Miller* that should preclude Appellant from this legal right, and the Examiner has not provided guidance with regard to any rationale to the contrary. Appellant therefore strongly asserts that the Board should overturn the Examiner’s rejection under 35 U.S.C. §§ 102(a), 102(b), and 102(e), and allow the claims as pending.

D. Argument: The Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 11 –15, 17 – 20, and 22 - 31 as obvious over US Patents to Calderas and Smith et al., in combination with Shibata et al., McGaughey, or Harris, further in light of Muhler and McDonald, under 35 U.S.C. § 103 (a).

As discussed above in the review of the Prior Art, Calderas and Smith teach low pH beverages containing the polyphosphates of the present claims. There is no teaching or suggestion in these two patents of dental erosion or the prevention thereof. Shibata, Harris, and McGaughey recite the use of condensed phosphates *at elevated pH in the diet for treatment of caries, not dental erosion*. Muhler and McDonald disclose only the use of monosodium dihydrogen phosphate ("MDP", NaH_2PO_4) for use in treating dental erosion. MDP is a simple, non-polymeric, ionic phosphate form which is unrelated, and does not encompass, the polyphosphate compounds utilized in the present invention. Accordingly, neither Muhler nor McDonald disclose or suggest the use of the present polyphosphate compounds for treatment against dental erosion. Moreover, it is helpful to remember with regard to Shibata, McGaughey, and Harris, that dental caries is caused by bacterial attack on teeth, see Shibata, p. 809 paragraph 1. Dental erosion, on the other hand, is a physical process involving the wearing away of tooth enamel, see the Abstract of McDonald. Caries and erosion have different causes, different cures and different methods of prevention. The teachings of one field of art do not necessarily translate into the other field.

To establish obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success in making the modification. Finally, the prior art reference must teach or suggest all the claimed limitations and the reasonable expectation of success must both be found in the prior art and not based on Appellants' disclosure. See *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

It would have been non-obvious to one of ordinary skill to use the recited polyphosphate compositions to treat dental erosion and to therefore provide kits which disseminate information regarding such treatment and the methods of providing such a treatment. Appellant asserts that, while the cited U.S. patents collectively disclose the polyphosphate compound utilized in the present claims, the patents fail to disclose, teach, or even suggest any use against dental erosion. Moreover, these references fail to suggest that the presently recited polyphosphate compounds would be useful as a substitute for the monosodium dihydrogen phosphate ("MDP", NaH_2PO_4) of Muhler and McDonald for the purpose of treating dental erosion. Nor is the teaching or suggestion of that necessary substitution present in Muhler and McDonald, which collectively teach one, and only one compound for preventing tooth erosion. Indeed, Appellant has amended independent Claim 11 to require that the claimed beverage composition comprises less than about 0.025% of orthophosphate (*i.e.*, MDP), by weight of the composition. This is reflective of

Appellant's unique and surprising discovery that the recited linear polyphosphates have effective utility against dental erosion.

The Examiner cites *In Re Schaumann*, 197 USPQ 5 (CCPA 1978) to support the present obviousness rejection, stating that the use of the present polyphosphate compounds would be immediately envisioned, and thus obvious, based on the decision of *Schaumann* and either the Muhler or McDonald references. Respectfully, the Examiner's dependence on *Schaumann* is misplaced and flawed. In *Schaumann*, the CCPA held that a genus can anticipate a claim to a species given the right set of circumstances. Appellant asserts that *Schaumann* has no applicability to the present case (under any set of circumstances), given that the polyphosphate compounds, which have a specific chemical structure as set forth in the claims, cannot in any way be classified as a species of MDP. MDP is, itself, a single compound and could never be considered by anyone skilled in the art as a "genus". Accordingly, the present Claims cannot be considered obvious based on Muhler or McDonald because there is no specific, general, or even implicit disclosure of the use of the present polyphosphate compounds against dental erosion.

Additionally, the present claims are nonobvious over either of Muhler and McDonald because these references fail to explicitly or implicitly disclose or even suggest the use of the defined polyphosphate compounds recited in Appellant's pending claims. One of ordinary skill would not have been led to substitute the presently recited polyphosphate compounds for the MDP – there is certainly no disclosure in Muhler or McDonald to suggest this substitution. Indeed, the presently recited polyphosphate compounds and MDP bear little resemblance structurally, as the former is a polymer and the latter is a free ionic species.

Taken together, therefore, the Examiner's cited combination of references fails to teach or even suggest the presently claimed kits. Firstly, and following the dictates of the law regarding non-obviousness, there would have been no motivation or suggestion in the references to make any modification which would arrive at the present kits or methods. The present kit and method claims require beverage compositions having acidic pH and comprising the defined linear polyphosphates and explicitly less than about 0.025% orthophosphate, all together with information that these acidic beverage compositions provide treatment against dental erosion. This is unexpected in light of the combined references, and in view of the literature generally, which would preclude any motivation to modify. Secondly, but similarly, there would have been no reasonable expectation of success for the same foregoing reasons. Finally, *the combination of references fails to teach or suggest all of the claimed limitations*, particularly with regard to the definition of the linear polyphosphate compound, the acidity of the beverage composition, and the surprising information associated therewith. Respectfully, the Examiner has therefore failed to establish any obviousness of the presently claimed kits.

Appellant also respectfully traverses the rejection of the present claims in view of Muhler or McDonald based on *In re Haller*, 73 USPQ 403 (CCPA 1947). The Examiner has cited *Haller* for the premise that novelty cannot be predicated on printed instructions. The *Haller* decision is discussed in detail above with regard to the anticipation rejection. Those arguments are equally valid here, especially the quote from footnote 8 of *In re Gulack*, where the Court of Appeals for the Federal Circuit states (emphasis added):

“A “printed matter rejection” under § 103 stands on questionable legal and logical footing. Standing alone, the description of an element of the invention as printed matter tells nothing about the differences between the invention and the prior art or about whether that invention was suggested by the prior art. A printed matter rejection is based on case law antedating the 1952 patent act, employing a point a novelty approach....The 1952 act legislatively revised this approach through its requirement that the claim be viewed as a whole in determining obviousness.”

The rejection based on *Haller* relies on the premise that the portion of the kit claims relating to “information” and the treatment steps of the present method claims can be ignored because they allegedly add no patentable weight. If this were true, and Appellant strongly asserts that it is not, the present reject would be a valid one. But the Examiner ignores the present law in the area of printed matter. When the law is correctly applied to the present claims, and the subject matter of the claims as a whole is considered, the claims are not obvious over the combination of references relied upon by the Examiner.

For all of the foregoing reasons, Appellant therefore asserts that the claimed kits and methods are non-obvious over the cited references in view of the consistent controlling authority. Appellant therefore requests that the Board overturn this rejection and promptly allow the claims.

CONCLUSION

It is respectfully submitted that the Examiner’s rejection of Claims 11 –15, 17 – 20, and 22 – 31 under 35 U.S.C. §§ 102 (a), (b) and (e) and 103(a), in view of numerous prior art references is improper. For all of the foregoing reasons, it is respectfully asserted that the information and method steps of the present claims must be given patentable weight, and that when these limitations are considered, the claims are indeed patentable over the prior art. Reversal of these rejections is therefore respectfully requested.

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Application Number 39/489,310
Attorney Docket Number 7922
Amendment dated June 16, 2003

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Respectfully submitted,
For: GARY (NMN) STEPHENSON

By 

S. Robert Chuey
Attorney for Appellants
Registration No. 39,140
Telephone: (513) 634-0102

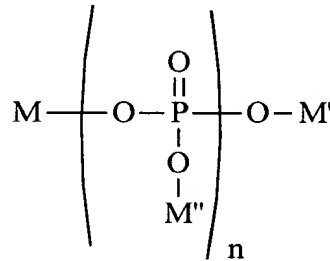
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APPENDIX

11. A kit comprising:

- (a) a beverage composition having a pH of less than about 5; wherein the beverage composition comprises a compound having the structure:



wherein n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium, and wherein the beverage composition is substantially free of calcium and fluoride and comprises less than about 0.025% of orthophosphate, by weight of the composition; and

- (b) information that use of the beverage composition provides treatment against dental erosion.

12. A kit according to Claim 22 wherein the beverage composition has a pH from about 2 to about 4.5.

13. A kit according to Claim 12 wherein the beverage composition further comprises a sweetener.

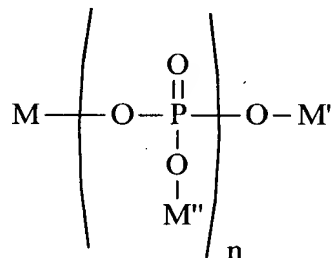
14. A kit according to Claim 13 wherein M, M', and M'' are each sodium.

15. A kit according to Claim 14 wherein n is an integer averaging from about 10 to about 30.

17. A kit according to Claim 15 wherein n is an integer averaging from about 13 to about 25.

18. A kit according to Claim 17 wherein the beverage composition has a pH from about 2.7 to about 3.5.

19. A kit according to Claim 18 wherein the beverage composition comprises from about 0.1% to about 20% of the sweetener, by weight of the composition.
20. A kit according to Claim 19 wherein n is an integer averaging about 19 to about 25.
22. A kit according to Claim 11 wherein the beverage composition comprises from about 0.001% to about 0.5% of the compound, by weight of the composition.
23. A method of treating dental erosion comprising orally administering to a mammal a beverage composition having a pH of less than about 5;
wherein the beverage composition comprises a compound having the structure:



- wherein n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium, and wherein the beverage composition is substantially free of calcium and fluoride.
24. A method according to Claim 23 wherein the beverage composition has a pH from about 2 to about 4.5.
25. A method according to Claim 24 wherein the beverage composition further comprises a sweetener.
26. A method according to Claim 25 wherein M, M', and M'' are each sodium.
27. A method according to Claim 26 wherein n is an integer averaging from about 10 to about 30.
28. A method according to Claim 27 wherein the beverage composition has a pH from about 2.7 to about 3.5.

29. A method according to Claim 28 wherein n is an integer averaging from about 13 to about 25.
30. A method according to Claim 29 wherein the beverage composition comprises from about 0.1% to about 20% of the sweetener, by weight of the composition.
31. A method according to Claim 30 wherein n is an integer averaging from about 19 to about 25.